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Joan Claybrook, President

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

August 13, 2004

Re: Docket #2004N-0264

Dear Secretary Thompson,

Public Citizen welcomed your announcement in January that the Food and Drug Administration (FDA) planned to close the loopholes in current animal feed regulations. But the proposals put out in the Federal Register earlier this summer are, in addition to being long overdue, regrettably weak.

Given the track record of the FDA in enforcing existing feed regulations and the potential for commingling of prohibited and allowable proteins at rendering plants, feed mills, and farms, we believe that the feed ban should be strengthened. This could be done by:

- prohibiting Specified Risk Materials for all animal feed, including pet food.
- prohibiting the use of all mammalian and poultry protein, including cattle blood and blood products and poultry litter, in ruminant feed. This is especially prudent in light of the fact that ruminants and many other food animals are fed animal protein simply as a way to hasten weight gain, not because of any dietary requirement.
- prohibiting material from downer animals and dead stock from use in all animal feed.

In answer to the specific questions raised in the Federal Register:

3. Necessity of Removing SRMs from Animal Feed.

We feel that the prohibition of SRMs from all animal feed is a sensible step, given the potential for cross contamination within feed production facilities and on-farm mistakes.

As the International Review Team pointed out:

“Epidemiological investigations in the UK in particular highlighted the dangers to cattle of infection through the consumption of feed that had been contaminated accidentally when manufactured in premises that legitimately used mammalian meat and bone meal in feed for monogastric species (pigs and poultry).”

Additionally, we feel that keeping SRMs out of feed destined for other animals is an appropriate way to deal with the risk that BSE could cross the species barrier. This is especially important if ruminant feed continues to contain protein from other mammals and poultry.

4. Definition of SRMs

We believe that the list of materials which qualify as SRMs should include those materials from all ages of cattle, not just those over 30 months. We believe this should be the definition for SRMs when it comes to both human and animal food.

5. Methods of SRM Verification

We are not aware of any practical methods for verifying that animal feed or feed ingredients are free of SRMs, other than requiring feed producers not to accept SRMs from slaughterhouses or other facilities, and enforcing this requirement with adequate government inspections.

6. Prevention of SRM Cross Contamination

If SRMs are prohibited for use in animal feed, any products which are still permitted to contain SRMs must be segregated and produced on dedicated lines that are separate from those producing any animal feed. Given the durability of prions and their resistance to most forms of sterilization, it is imperative that SRMs never come into contact with surfaces or machinery that will later come into contact with animal feed.

8. Human Contact with Pet Food

We are not aware of any data on the extent of human contact, including ingestion, of pet food. But there is sufficient anecdotal evidence that the practice does occur, and given the lack of rules requiring any BSE warnings on pet food, we feel that this justifies including pet food in the list of products for which SRMs should be prohibited.

The use of salvage pet food product as an ingredient in other animal feed presents a potential route back to ruminants. Therefore, pet food should not contain SRMs.

9. Need for Designated Facilities to Prevent Cross Contamination

We refer again to the report by the IRT, which stated that:

“Epidemiological investigations in the UK in particular highlighted the dangers to cattle of infection through the consumption of feed that had been contaminated accidentally when manufactured in premises that legitimately used mammalian meat and bone meal in feed for monogastric species (pigs and poultry).”

Since SRMs were presumably the material in the mammalian meat and bone meal which caused the cross contamination, we feel that this quote from the IRT illustrates how vital it is to establish designated facilities to prevent such contamination.

12 and 13. Necessity of Banning Mammalian and Avian MBM in Ruminant Feed

While removing SRMs from all animal feed is an important part of a truly protective feed ban, it is also necessary to keep mammalian and avian protein out of ruminant feed as an extra precaution. Given that other animals can be fed ruminant protein, it is vital that these animals not be fed back to ruminants. A ban on mammalian and avian protein, including poultry litter and plate waste, is a necessary step to ensure that non-ruminants do not serve as an intermediate step in the process of ruminants consuming ruminant material.

15. Bovine Blood

In early August, researchers reported in the Lancet that prions had been found in a second person who had contracted vCJD, the human form of BSE, from a contaminated blood transfusion. This suggests that our understanding of the role of blood in transmitting prions is still developing. Until this is fully understood, it seems prudent to keep cattle blood out of ruminant feed.

16. Plate Waste

Plate waste is inspected meat products which have been cooked and offered for human consumption and then processed for animal feed. Because plate waste could include beef (and potentially SRMs which were not properly removed during processing), it could serve as a route for ruminant material to be fed back to ruminants. Additionally, if the feed regulations are strengthened to prohibit all mammalian and poultry protein from ruminant feed, plate waste would also have to be prohibited, as those materials would likely be found in most plate waste.

17. Poultry Litter

Because poultry feed can contain ruminant material, and spilled and undigested feed is a component of poultry litter, including poultry litter in ruminant feed could be serving as a route for ruminant material to make it back into ruminant feed. Therefore, poultry litter should be prohibited from ruminant feed.

Another aspect of the feed regulations that must be strengthened is the record-keeping requirement. Currently feed producers, suppliers, and users must maintain records for one year. This is not adequate for a disease with an incubation period that can last more than a decade. Records should be maintained for at least 10 years.

No matter how strong the regulations on animal feed are, they cannot protect public health without adequate enforcement. As recently as January 2002, the U.S. Government Accountability Office (GAO) concluded that the FDA "does not know the full extent of industry compliance." Adequate attention and resources must be devoted to enforcing the feed ban for any changes made to the rules to be meaningful.

The public has already waited long enough for the FDA to close the loopholes in the BSE-firewall. We urge you to prohibit Specified Risk Materials for all animal feed; prohibit the use of all mammalian and poultry protein in ruminant feed; and prohibit material from downer animals and dead stock from use in all animal feed without any further delay.

Sincerely,

A handwritten signature in black ink, appearing to read "Wenonah Hauter". The signature is fluid and cursive, with a long horizontal stroke at the end.

Wenonah Hauter
Director
Public Citizen's Energy and Environment Program